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10/034,336	12/28/2001	Gopinathan K. Menon	680.0049USU	8349

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EXAMINER

COE, SUSAN D

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 11/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

**Office Action Summary**

Application No.

10/034,336

Applicant(s)

MENON ET AL.

Examiner

Susan Coe

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 17-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-30 are currently pending.

#### ***Election/Restrictions***

2. Applicant's election with traverse of Group I, claims 1-16 in Paper No. 6, dated October 21, 2002 is acknowledged. The traversal is on the ground(s) that the groups are related because all of the groups depend from the composition claims of group I. This is not found persuasive because while the search of all of the groups might overlap to some extent, they would not necessarily be coextensive in regards to the methods of using the composition because the composition can be used for different purposes other than those claimed by applicant.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 17-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
4. Claims 1-16 are examined on the merits.

#### ***Claim Objections***

5. Claims 1, 11-13, and 16 are objected to because of the following informalities:  
"Rhodeola" in these claims appears to be a misspelling of "Rhodiola". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6-9, 11, 12, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are considered indefinite because claim 1 states that *Azadiracta* is a required ingredient in the composition (line 11); however, claims 6-9, 11, 12, and 16 do not include *Azadiracta* in the composition.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-9 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over UK Pat. Appl. No. GB 2 000 971 A, Japanese Pat. Appl. No. 3-176414 A, Derwent abstract of Russian Pat. No. 2025119 C1, and Sabinsa Corporation Webpage ([www.sabinsa.com/news/June2001.htm](http://www.sabinsa.com/news/June2001.htm)).

Applicant's claims are drawn to a composition comprising an *Azadiracta* seed extract and at least one of *Gynostemma*, coconut water, and *Rhodiola*.

GB '971 teaches using an *Azadiracta* (neem) seed extract to treat dandruff and balding.

JP '414 teaches using *Gynostemma* to treat dandruff and alopecia.

RU '119 teaches using *Rhodiola* to improve hair and prevent hair loss.

The Sabinsa webpage teaches using coconut water in hair care formulations (see page 2, "Cococin" section).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in hair care compositions. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art.

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In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in hair care compositions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating a hair care composition. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize.

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Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The references also do not specifically teach adding all of the additional ingredients in claim 14. However, all of these ingredients are known in the art to be suitable for adding to a topical composition. Therefore, a person of ordinary skill in the art would have been motivated to add these ingredients to the composition taught by the combination of the references.

The references do not specifically teach formulating the composition in the forms claimed by applicant in claim 15. These forms of administration are well known in the art to be acceptable forms for a topical composition. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulate the composition taught by the reference in the forms claimed by applicant.

8. Claims 1 and 10 rejected under 35 U.S.C. 103(a) as being unpatentable over UK Pat. Appl. No. GB 2 000 971 A, Japanese Pat. Appl. No. 3-176414 A, Derwent abstract of Russian Pat. No. 2025119 C1, and Sabinsa Corporation Webpage ([www.sabinsa.com/news/June2001.htm](http://www.sabinsa.com/news/June2001.htm)) as applied to claims 1-9 and 11-16 above, and further in view of US Pat. No. 5,698,423.

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As stated above, GB '971, JP '414, RU '119, and the Sabinsa webpage teach the claimed composition. However, the references do not specifically teach using a neem seed culture in the composition. US '423 teaches that using a neem seed culture to create a pharmaceutical extract is beneficial over using a straight neem seed extract because it eliminates contaminants present in the straight seed extract (see column 4, lines 38-42). Based on this teaching, a person of ordinary skill in the art would have reasonably expected that the neem seed composition taught by GB '971 could be improved if it was created in the manner claimed by US '423. Therefore, an artisan of ordinary skill would have been motivated to use a neem seed extract created using a cell culture extract based on the teaching of US '423 that this method of extraction creates a superior product.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

9. Claims 1-9 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over UK Pat. Appl. No. GB 2 000 971 A, Japanese Pat. Appl. No. 3-176414 A, Derwent abstract of Russian Pat. No. 2025119 C1, and German Pat. Appl. No. 4312109 A1

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GB '971 teaches using an *Azadiracta* (neem) seed extract to treat dandruff and balding.

JP '414 teaches using *Gynostemma* to treat dandruff and alopecia (see English abstract).

RU '119 teaches using *Rhodiola* to improve hair and prevent hair loss.

DE '109 teaches using coconut milk to prevent hair loss (see English abstract). Coconut milk is considered to be the same substance as coconut water.

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in hair care compositions. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

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10. Claims 1 and 10 rejected under 35 U.S.C. 103(a) as being unpatentable over UK Pat. Appl. No. GB 2 000 971 A, Japanese Pat. Appl. No. 3-176414 A, Derwent abstract of Russian

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Pat. No. 2025119 C1, and German Pat. Appl. No. 4312109 A1 as applied to claims 1-9 and 11-16 above, and further in view of US Pat. No. 5,698,423.

As stated above, GB '971, JP '414, RU '119, and the DE '109 teach the claimed composition. However, the references do not specifically teach using a neem seed culture in the composition. US '423 teaches that using a neem seed culture to create a pharmaceutical extract is beneficial over using a straight neem seed extract because it eliminates contaminants present in the straight seed extract (see column 4, lines 38-42). Based on this teaching, a person of ordinary skill in the art would have reasonably expected that the neem seed composition taught by GB '971 could be improved if it was created in the manner claimed by US '423. Therefore, an artisan of ordinary skill would have been motivated to use a neem seed extract created using a cell culture extract based on the teaching of US '423 that this method of extraction creates a superior product.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

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11. No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Susan Coe, Examiner  
October 30, 2002

  
**LEON B. LANKFORD, JR.**  
**PRIMARY EXAMINER**